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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,882	03/01/2002	Syed Z. Salahuddin	015280-212210US	8486

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/06/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/087,882	Applicant(s) Salahuddin et al
	Examiner A. R. SALMI	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *7/26/02; 3/1/02*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-12* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 4-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

The receipt of preliminary amendment of 3/01/2002, is acknowledged. Claim 3 has been canceled. Claims 4-12 have been added. Claims 1, 2, 4-12 are present.

Claims 1, 2, 4-12 are pending.

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Specification

The amendment filed 3/1/02 is objected to under 35 U.S.C. 132 because it introduces **new matter** into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 12 recites "human herpes virus is present on an intact herpes virion", no disclosure of intact herpes virion is not present.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The recitation of " human herpes virus is present on an intact herpes virion" is not present.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The correction of the priority information is respectfully requested. Applicants request for updating the information filed 3/1/2002 is noted. However, the information is incomplete and incorrect i.e file wrapper does not match, and at times the information is/ are duplicated, for example application 07/228,550 was not filed August 4, 1998. The information does not match the file history. Please review the information thoroughly, and correct accordingly. In addition, please also include the reissue information and patent no. 6,054,283.

Reissue Applications

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Oath/Declaration

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1, 2, 4-12 are rejected as being based upon a defective Oath under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

Information Disclosure Statement

Applicants have not furnished the Office with a new 1449 list which lists all the references cited on the U.S. Patent No. 6,054,283. Please provide a new 1449 list.

Claim Rejections - 35 USC § 112

Claims 1-2, 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite, the intended region or regions where the antibody is binding should be identified. Is the antibody to the capsid proteins intended? Moreover, the intended metes and bounds of the antibody or antibodies are not defined. The claims is not directed to isolated antibodies against the capsid protein of isolated HHV-6 virus identified as ZVH14 with ATCC accession No. 40,247. The claim antibodies read on any and all herpes viruses. The proviso language that is present in claim 1 has no bearing on antibodies binding to herpes viruses. The conditions of hybridization and antibody binding are separate from each other. If there is a common epitope between ATCC accession No. 40,247 virus and a CMV the antibody would bind to both. But the disclosure has not provided the metes and bounds of said antibodies. In addition, the claim is vague and indefinite, since the "stringent" is a relative term. The conditions wherein the applicants regard as "stringent' should be specifically recited. What applicants regard as stringent might be considered as non-stringent to others. The claim has been

interpreted in light of the specification and since the specification does not set forth the intended conditions of "stringent conditions" nor the metes and bounds of the intended antibodies the claim is vague and indefinite. Still further, the claim is confusing for recitation of "wherein said first nucleic acid" , which said first nucleic acid is intended? There is no antecedent bases for said limitation in the claim. This affects the dependent claims.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the intended antibodies are not defined. The intended human herpes virus antigen(s) are not provided. Amending the claims to the capsid antigens of ATCC accession No. 40,247 would obviate this rejection.

Claim 4 is vague and indefinite, the intended "human herpes virus antigen" is/are not defined. Which human herpes virus antigen is intended, is HSV-1 intended? The claim should indicate clearly that the intended virus is indeed ATCC accession No. 40,247 only. The breathe of the part "(a)" is broader that the preamble, it refers to "a human herpesvirus" and not the said human herpes virus. This affects the dependent claims 5-12.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP

§ 2172.01. The omitted elements are: the intended human herpes virus antigen(s) is/ are not provided, Isn't the virus identified as ATCC accession No. 40,247 an intact virus?

Claim 12 is vague and indefinite. The recitation of "human herpes virus is present on an intact herpes virion" is confusing, what does this mean? What is the difference between the product of claim 12, and the product of claim 4 (ATCC NO. 40,247)? Isn't the deposited herpesvirus identified as ATCC NO. 40,247 an intact virus?

Claim Rejections - 35 USC § 112

Claims 1, 2, 4-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody directed against the capsid glycoproteins of a deposited HHV-6 virus identified as ATCC accession No. 40,247, and method of utilizing the capsid antigens of the ATCC accession No. 40,247 virus only in diagnostic method(s) for detecting the presence of antibodies against said virus wherein antigens form a complex with antibodies in a biological sample, does not reasonably provide enablement for all antibodies against all HHV-6 types or against antibodies against any and all herpes viruses. In addition, the specification does not provide enablement for a broad method of utilizing antibodies that are present in a sample to be utilized in any and all methods to form a complex with all herpesvirus antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in

scope with these claims. Applicants are reminded that this field is rather unpredictable, especially given the priority date claimed. First, no hybridization conditions is taught for the one ordinary skill in the art to determine which sequences would be encompassed within the scope of the claimed invention. Absent clear teaching undue experimentation would be required to enable the full scope of the claims. Second, the antibody recognition of an epitope on an antigenic polypeptide and its level of binding specificity has no bearing on stringent hybridization assay. Antibody specificity mostly concerns itself with polypeptide folding and availability of antigenic regions. In other words, whether a piece of DNA can hybridize to another piece of DNA does not provide teaching for characterization of the antibodies and how one of skill in the art would know what is and isn't encompassed. To characterize the antibodies absent any teaching by the disclosure one of ordinary skill in the art would be required to conduct large quantity of experimentations, and still would not know what antibodies are ascertained within the scope of claimed invention. Third, the proviso language is directed to hybridization. The proviso limitation does not cover the myriads of isolated antibodies that would specifically bind the viruses recited in parts (a) to (e).

Fourth, with regard to the scope of method of detecting, the disclosure is rather deficient in providing adequate teaching. Applicants are requesting patent protection for all types of antibodies that have never been possessed or described to be utilized in a detection assay to detect viral antigens that have not be described at all. The scope of claim 2 is not directed to antibodies against the antigens of the deposited virus. It's rather directed to antigens of any and all HHV-6

types, as well as any and all antibodies. Absent adequate teaching undue experimentation would be required.

Fifth, the scope of newly added claims are broad. The method of claim 4 is requesting patent protection for antigens directed against any and all human herpes virus antigens. No such teaching has been provided and absent teaching one ordinary skill in the art would not be able to enable the broad scope of the method of detecting. The claim is not directed to the antigens of the deposited herpesvirus.

Therefore, scope of the claims are directed to elements for which applicants have not provided adequate teaching. Applicants have general statements, however with regard to an unpredictable field, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of all antibodies for all isolates, and their utilization in a detection method for all antigens. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant can not rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that

undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to multitude of antibodies, and antigens. In contrast, the specification describes the deposited virus as identified by ATCC Accession No. 40,247 only, and applicants are only entitled to antibodies against the capsid proteins of the said deposited virus, and a method of utilizing the antigens of the said deposited virus to identify the antibodies against the said virus, only. Applicants do not describe other molecules encompassed by the claims, and the structural features that distinguish all such antibodies and antigens from other immunoglobulin and antigens are not provided neither the method of their use. If applicants were not in possession of the antibodies that are now being claimed then they were not is possession of the method of using them either. In order, to practice the method of claims one should be in possession of the antibodies and antigens.

Hence, Applicants have not, in fact, described the antibodies and/or antigens encompassed within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed sequence "comprising", it is not clear the Applicant was in possession of the genus claimed at the time this application was filed.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged

> conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Middeldrop et al (Journal of Clinical Microbiology, Oct. 1984, pp. 763-771), in view of and further substantiated by teaching of Lawrence et al (Journal of Virology, 1990, pp. 287-299).

The claims are directed to multitude of antibodies and their method of use in various detection assay methods. Middeldrop et al taught antibodies and method of using to detect the presence of antigens against cytomegalovirus (CMV) (see the abstract). The product now claimed is the same taught by the Middeldrop et al. In addition, it is well known in the art that CMV and HHV-6 are closely related and share antigen similarities as evidenced by Lawrence et al (see the abstract, and page 297, right column lines 1-15). The antibodies are known to have long range of detect ability. Hence, the product that is

now being claimed was known in the prior art and anticipates the claimed invention. In addition, Middeldrop et al utilized the antigens of CMV in a detection assay (see page 764, left column, last paragraph). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Rodgers et al (Journal of general Virology, 1985, Vol. 66, pp. 2045-2049), in view of and further substantiated by teaching of Lawrence et al (Journal of Virology, 1990, pp. 287-299).

Rodgers et al disclosed specific antibodies against human cytomegalovirus and assessed by various detection assays and methods (see the abstract). In addition, it is well

known in the art that CMV and HHV-6 are closely related and share antigen similarities as evidenced by Lawrence et al (see the abstract, and page 297, right column lines 1-15). The antibodies are known to have long range of detect ability. Hence, the product that is now being claimed was known in the art, and hence anticipates the claimed invention. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

10/28/2002

ALI R. SALIMI
PRIMARY EXAMINER